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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,518	09/14/2005	Stephen P. Massia	112624.00022	1335
26707 7590 04/26/2007 QUARLES & BRADY LLP RENAISSANCE ONE TWO NORTH CENTRAL AVENUE PHOENIX, AZ 85004-2391			EXAMINER LUKTON, DAVID	
			ART UNIT	PAPER NUMBER
			1654	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/26/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/549,518

Applicant(s)

MASSIA ET AL.

Examiner

David Lukton

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 2-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

Applicants' election of Group I (claims 1, 2, 4-6) without traverse is acknowledged. Also acknowledged is applicants' response to the "election of species" requirement. Applicants have elected a compound *per se* (as opposed to a composition), and more specifically the compound N<sup>6</sup>-(Arginyl)-Lysine.

Applicants have requested that claim 3 be rejoined with the elected claims. In the event that claim 1 is determined to be allowable, methods of making and using the allowable compound (or composition, as the case may be) will be rejoined for further examination.

Claim 1 is examined in this Office action; claims 2-12 are withdrawn from consideration.



Figure 1 is objected to. At the bottom of the page, a structure is provided in which the amide hydrogen atom is missing.



Claim 1 is rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- In claim 1, the phrase "the composition" lacks antecedent basis.

- Claim 1 is rendered indefinite as a consequence of the recitation of a "composition" (apart from the matter of antecedent basis). The claim could be interpreted to refer to a composition, such as that recited in claim 6, where a second component is affirmatively recited. Alternatively, the term at issue could be interpreted to refer to a "composition of matter". As it happens, there is no court opinion or statute which prohibits the use of this term in a claim. As a practical matter, however, the term "composition of matter" is never used by organic chemists in cases where the structure of the compound in question has been fully (or even partially) elucidated. The term at issue ("composition of matter") is sometimes used by geologists to refer to a rock of unknown composition, or perhaps the term is used by physicists in a general way. But again, in the context of organic chemistry, the term composition of matter is entirely inappropriate. In any case, claim 1 should be amended to make clear whether a single compound is intended, or a composition, and if a composition is intended, what else can or must be present?



The following is a quotation of the appropriate paragraphs of 35 U.S.C. §112 that form the basis for the rejections under this section made in this action.

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. §102(b) as being anticipated by Szokan, Gy. (*Biopolymers* 42(3), 305-318, 1997).

Szokan discloses (p. 314, column 1) the compound N<sup>6</sup>-(Arginyl)-Lysine.

Thus, the claim is anticipated.



Claim 1 is rejected under 35 U.S.C. §102(b) as being anticipated by Finot, Paul Andre ((*Advances in Experimental Medicine and Biology* 105(Nutr. Improv. Food Feed Proteins), 549-70, 1978)

Finot discloses (page 554) the compound N<sup>6</sup>-(Arginyl)-Lysine.

Thus, the claim is anticipated.

✦

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



DAVID LUKTON, PH.D.  
PRIMARY EXAMINER